

## **Remarks**

Claims 1 and 9 have been amended, claims 5 - 8 have been canceled. Claims 1-4, 9-10 are currently pending. Support for the amendments may be found in the amended claim and throughout the instant specification as noted below. No new matter has been added.

Applicants address the Examiner's remarks in the order presented.

### **Affirmation of Election of Group I**

The Examiner imposed a restriction requirement under 35 USC §121 and §372 to Group I (claims 1-6, 9-10) drawn to a method of identifying a compound capable of modulating the activity of Cathepsin Z in a cell and Group II (claims 7-8) drawn to a compound identified as capable of modulating the activity of Cathepsin Z and a pharmaceutical. A provisional election of Group I was made during a telephone conversation on October 16, 2007. Applicants affirm the election of Group I, claims 1-6 and 9-10. Applicants reserve the right to file divisional applications directed to the non-elected subject matter of the instant application.

### **Rejections under 35 USC §102(a)**

Claims 1-2, 5 and 9-10 are rejected under 35 USC §102(a) as allegedly being anticipated by Wisotzkey et al (US Application No. 20030159168, August 21, 2003). The Examiner contends Wisotzkey et al. teaches a method of identifying a compound capable of modulating Cathepsin Z activity in a cell comprising steps of: (a) measuring said cell's base level of Cathepsin Z in the absence of a candidate compound; (b) introducing said candidate compound; and (c) measuring said cell's level of Cathepsin Z activity in the presence of said candidate compound (abstract, [0020], [0024]) wherein said cell's level of Cathepsin Z activity is measured by measuring antigen presentation (examples 19 and example 20); further, the identified

candidate compound being useful for treating autoimmune disease such as rheumatoid arthritis [0015].

Claim 1 has been amended to recite “an antigen-presenting dendritic cell”. Support for this amendment is provided by original claim 6 as well as throughout of the instant specification, for instance in Figure 2. Claim 9 has been amended to be dependent from claim 1. Support for the amendment to claim 9 may be found in original claim 8. Thus, claims 2 and 9 are dependent from claim 1, claim 10 is dependent from claim 9, and claims 3 and 4 are dependent from claim 2. Wisotzkey et al. does not anticipate a method wherein the cell is an antigen-presenting dendritic cell. The abstract of Wisotzkey et al. does not recite a cell, paragraph [0020] focuses on the use of transgenic animals and mentions “cell-based assays” without description of which cells would be useful in the assay, paragraph [0024] does not discuss the use of cells, and example 19 discusses “a local inflammatory response mediated by leukocytes such as neutrophils, monocytes, macrophages and mast cells” [0257]. Since the Wisotzkey et al. reference does not teach all the elements of the claimed invention as now amended, it is submitted that the rejection under 35 USC 102(a) has been overcome and removal of the rejection is respectfully requested.

Claims 1-2, 5-6 and 9 are rejected under 35 USC §102(a) as allegedly being anticipated by Li et al (WO 2003/079982). The Examiner states Li et al. teaches identifying a compound capable of modulating Cathepsin Z activity in a cell comprising the steps of measuring said cell's base level of Cathepsin Z activity in the absence of candidate compound, introducing said candidate compound and measuring said cells level of Cathepsin Z activity in the presence of said candidate compound wherein Cathepsin Z activity is measured by measuring antigen presentation (see claims of Li et al.) and administering said candidate compound as a pharmaceutical for treating cancer (Li et al., pgs 5-7). Li et al. does not teach an antigen-presenting dendritic cell. Since Li et al. does not teach all the elements of the claimed invention as now amended, it is submitted that the rejection under 35 USC 102(a) has been overcome and withdrawal of the rejection is respectfully requested.

### Rejections under 35 USC §103

Claims 1-6, 5 and 9-10 are rejected under 35 USC §103(a) as allegedly being unpatentable over Wisotzkey et al (US Application No. 20030159168, August 21, 2003) in view of Copland et al. (Vaccine 21:883, 2003). Wisotzkey et al. was relied upon by the Examiner as set forth *supra*. The Examiner asserts that Copland et al. teach immature dendritic cells uptake antigen and express cell surface markers following incubation with FITC-conjugated antigen, enhanced cell surface marker expression after exposure to FITC-ovalbumin and after exposure to tetanus toxin-stimulated T cells. The Examiner contends that it would have been *prima facie* obvious at the time the instant invention was made to incorporate measuring autologous T-cell response to tetanus toxin in view of Wisotzkey et al. teaching a method of identifying a compound capable of modulating Cathepsin Z activity in a cell. Claim 1 has been amended to obviate this rejection. The references of Wisotzkey et al. and Copland et al. in combination do not teach or suggest a method of identifying a compound capable of modulating the activity of Cathepsin Z activity in an antigen-presenting dendritic cell. Thus, claim 1 and claims 2-4 and 9-10 which are ultimately dependent from claim 1, are non-obvious and patentable over the prior art.

Claims 1-10 are rejected under 35 USC §103(a) as allegedly being unpatentable over Thurmond et al. (WO 2002/21129) in view of Copland et al. (Vaccine 21:883, 2003) and Wisotzkey et al. Wisotzkey et al. and Copland et al. were relied upon by the Examiner as set forth *supra*. The Examiner asserts that Thurmond et al. teaches a method of identifying a compound capable of modulating the activity of Cathepsin S in a cell. The Examiner contends it would have been *prima facie* obvious at the time the invention was made to incorporate Cathepsin Z as taught by Wisotzkey et al. to the method of Thurmond et al. and incorporate measuring autologous T-cell response to tetanus toxin and measuring the cells capacity to present quenched FITC ovalbumen as taught by Copland et al. The amendment to claim 1 such that claim 1 recites "an antigen-presetning cell" obviates this rejection rendering claim 1 and dependent claims 2-6, 5 and 9-10 non-obvious and patentable.

Accordingly, it is submitted that the rejections under 35 USC §103(a) should be withdrawn and notice to that effect is respectfully requested.

Applicants respectfully submit that the application is now in condition for allowance and request notice thereof. Should the Examiner believe that an interview would advance prosecution of the instant application, Applicants invite the Examiner to contact the undersigned at 908-231-4757.

Respectfully submitted,

A handwritten signature in dark ink, appearing to read "Ann Marie Szczepanik", written over a horizontal line.

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